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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Rosenberg			
Serial No.	:	10/601,455	Art Unit	:	3761
Filed	:	June 23, 2003	Examiner	:	Deak, Leslie R.
Title	:	AN IMPLANTABLE MEDICAL DEVICE HAVING PRESSURE SENSORS FOR DIAGNOSING THE PERFORMANCE OF AN IMPLANTED MEDICAL DEVICE			

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/Eugene L. Szczecina, Jr./

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(Name of applicant, assignee, or Registered Representative)

Mail Stop Appeal Brief- Patents
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APPEAL BRIEF

Dear Sir:

This Appeal Brief is filed in response to the Notice of Appeal, which was filed by Appellant to the U.S. Patent & Trademark Office on August 16, 2006, and to the Notification of Non-Compliant Appeal Brief.

Real Party In Interest:

The real party in interest for this patent application is Codman & Shurtleff, Inc., 325 Paramount Drive, Raynham, MA 02767.

Related Appeals and Interferences:

There are no related appeals or interferences known to Appellant, the Appellant's legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims:

Claims 1-46 are pending and have been rejected.

Status of Amendments:

No amendments have been filed after the final rejection of March16, 2006.

Summary of Claimed Subject Matter:

The claimed subject matter based upon independent claims 1, 18, 24 and 37-40 is directed to an implanted medical device 10 including a housing 12 and a valve 14 disposed within housing 12. A first pressure sensor 16 is disposed within housing 12 upstream of valve 14. A second pressure sensor 18 is disposed within housing 12 downstream of valve 14. A CPU 20 is disposed within housing 12 and is electrically connected to first pressure sensor 16 and second pressure sensor 18. In one embodiment, first and second pressure sensors 16, 18 are disposed within housing 12 along with valve 14. See Page 3, line 27 – Page 4, line 2 and Figure 3.

Alternatively, as recited in independent claim 25, a differential pressure sensor 50 is disposed in housing 12 along with valve 14. See Page 4, lines 11-19 and Figures 5 and 6.

With respect to independent claim 21, to communicate the measured pressure information to an external device, CPU 20 compares the pressure measured by first pressure sensor 16 to the pressure measured by second pressure sensor 18 and wirelessly communicates these compared pressures to the external device. Alternatively, as recited in independent claim 24, CPU 20 may wirelessly communicate the absolute value of the

pressure measured by first pressure sensor 16 and second pressure sensor 18 to the external device. See Page 4, lines 25-28.

To diagnose the performance of the implanted medical device 10, the pressure measured by the first pressure sensor 16 is compared to the pressure measured by the second pressure sensor 18. The compared pressures are then wirelessly communicated to an external device. Alternatively, as recited in independent claim 37, the pressure detected by the first pressure sensor 16 and second pressure sensor 18, or by the differential pressure sensor, is determined by CPU 20. This CPU determined information is then wirelessly communicated to an external device. Alternatively, the external device can compare the pressures detected by the first and second pressure sensors 16, 18 as recited in independent claim 38. In a further alternative, a signal from the first pressure sensor 16 and second pressure sensor 18 is generated by CPU 20, as recited in independent claim 39. These signals are compared and a signal representative of the difference in pressure between the pressure measured by the first pressure sensor 16 and the pressure measured by the second pressure sensor 18 is generated by CPU 20. Thereafter, this signal representative of the difference in pressure to an external device is wirelessly communicated to the external device by CPU 20. See page 4, line 28-page 5, line 10 and page 5, line 31 – page 6, line 9.

Grounds of Rejection To Be Reviewed On Appeal:

1. **The disclosure stands objected to for not enabling a "means for being…powered" by the various claimed power sources.**

2. **Claims 15-17 and 34-36 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite.**

3. **Claims 1-5, 21, 24, and 38-40 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,585,677 to Cowan, Jr. et al. ("Cowan").**

4. **Claims 6-14, 18-20, 22-23, 25-33, 37 and 41-46 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cowan.**

5. **Claims 15-17 and 34-36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cowan in view of U.S. Patent No. 6,061,596 to Richmond et al.**

Argument:

1. **The disclosure stands objected to for not enabling a "means for being...powered" by the various claimed power sources.**

The Examiner objects to the disclosure because, in the Examiner's opinion, Appellant has failed to set forth what structure is meant by the means for being non-invasively powered using RF, acoustics or optical waves. Appellant's respectfully disagree. Page 6, line 16 of the original specification clearly states that the CPU and sensors are preferably non-invasively powered by the external device using RF telemetry, or by using acoustic or optic methods. CPU 20 includes an antenna 28 to permit the CPU to wirelessly communicate with an external device in a manner known to those skilled in the art (page 4, lines 4-7). Thus, Appellant disagrees with the Examiner's statement that the specification "discloses no structure capable of carrying out the powering function." The combination of the structural elements of the external device and the antenna and CPU permit the CPU and sensors to be non-invasively powered in a manner known to those skilled in the art.

2. **Claims 15-17 and 34-36 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite.**

The Examiner states that the scope of claims 15-17 and 34-36 is unclear because the appear to invoke 35 U.S.C. §112, sixth paragraph language, but fail to do

so because they recite "a material or structural limitation for carrying out the "means for being non-invasively powered." Appellant respectfully disagrees. The recitations recited in dependent claims 15-17 and 34-36 are classic §112 sixth paragraph language. For example, claim 15 and 34 recite that "the CPU has means for being non-invasively powered using RF." The claims use the phrase "means for". The "means for" phrase is modified by functional language, i.e., "being non-invasively powered". Finally, the phrase "means for" is not modified by sufficient structure, material or acts for achieving the specified function. As stated above, the combination of the structural elements of the external device, the antenna and CPU permit the CPU and sensors to be non-invasively powered by the external device. None of the structural elements of the external device, antenna, CPU nor the sensors are recited in these claims. The claims do add the phrase "using RF", "using acoustics" and "using optics", but this is not the recitation of sufficient structure for achieving the specified function. Thus, this rejection should be reversed.

3. Claims 1-5, 21, 24, and 38-40 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,585,677 to Cowan, Jr. et al. ("Cowan").

The Examiner maintains that Cowan discloses a shunt with catheters 28, 34, a master control unit 24 that comprises a valve-guage assembly 52 with pressure gauges or sensors, a valve to control fluid flow, and a microprocessor that receives and interprets inputs from the pressure gauges to control the valve and fluid flow.

All of the independent claims of the present invention (claims 1, 18, 21, 24, 25 and 37-40) recite that the first and second pressure sensors are disposed within the housing along with the valve, or they recite that a differential pressure sensor is disposed in the housing with the valve. This is structure that is neither taught nor suggested by Cowan. Referring to Figs. 1 and 2 of Cowan, and the corresponding disclosure, the only housing illustrated and described is the master control unit 24. A valve gauge assembly 52, 52a is disclosed as being housed within the master control unit 24 (see, for example, col. 5, lines 12-13). Valve gauge assembly 52, 52a is disclosed as including a pressure gauge and a valve. Cowan does not disclose, however, if this pressure gauge is disposed

upstream or downstream with respect to the valve. Cowan also discloses that a ventricular gauge 54 is located proximal to the ventricular catheter 32 and is connected to the portion of assembly 52 housed within master control unit 24 via a control line 56. The adjective "ventricular" refers to the ventricles of the brain. Ventricles are cavities in the brain that are filled with cerebrospinal fluid. It is precisely this fluid that is to be drained by Cowan's device. In practice, the valve housing is disposed outside of a patient's skull, and fluid communication with a patient's ventricles (obviously located within the skull) is achieved by way of a ventricular catheter. Thus, Cowan makes it abundantly clear that ventricular gauge 54 is disposed outside of the master control unit housing 24. Cowan also teaches that a control line 56 is used to connect gauge 54 and master control unit 24. Therefore, Cowan teaches away from including a second pressure sensor within the housing of master control unit 24. Accordingly, the present invention is neither taught nor suggested by Cowan.

The Examiner states that the claims recite limitations drawn to the mode of operation of the controller. The Examiner maintains that these are recitations of intended use and are therefore not limitations of the claims. By amendment, Appellant has changed these limitations to be means plus function clauses. As such, the prior art relied upon by the Examiner must include structure that performs the recited function to anticipate the claimed invention. The Examiner has admitted that Cowan fails to disclose that Cowen's microprocessor performs the claim limitations. The Examiner does state that Cowan's device "may be programmed to perform the operations claimed by applicant", but this is based on pure speculation and the use of hindsight by the Examiner. For example, claims 3 and 4 recite that the CPU has means for calculating a differential pressure between the first pressure sensor and the second pressure sensor. There is no teaching or suggestion in Cowan for the processor to calculate a differential pressure between the two gauges. In fact, in the first paragraph at the top of column 6, Cowan states that the processing units of the valve-gauge assembly 52 and the diagnostic unit 60 are both connected to a transmitter 64, which emits that information to an external computing device. Cowan stresses that to reduce battery consumption, transmitter 64 emits as a low power level, and the external computing device uses the information to either automatically diagnose any malfunction or infection, and/or simply

pass along the data to the patient's doctor for review and analyses. Thus, because Cowan in concerned about preserving battery life, Cowan actually teaches away from having the internal processor perform additional programs. Appellant's also note that Cowan includes no teaching whatsoever that the internal processor can be powered non-invasively.

4. Claims 6-14, 18-20, 22-23, 25-33, 37 and 41-46 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cowan.

The Examiner maintains that it would have been obvious to add a third and fourth pressure sensor to Cowan's device. The Examiner also concludes that it would have been obvious to place the CPU inside or outside of the housing. Finally, the Examiner concludes that it would have been obvious to combine Cowan's pressure sensors into a differential pressure sensor.

The Examiner also concludes that it would have been obvious to add a third and fourth pressure sensor to Cowan's device because to do so is a mere duplication of the essential working parts of a device. Appellant respectfully disagree. Appellant has strategically placed the third and fourth pressure sensors at the distal ends of the inlet catheter and the outlet catheter. Thus, because of the placement of these additional pressure sensors, the present invention permits the doctor to non-invasively determine the source of malfunction of the shunt to a much greater degree of certainty. Thus, adding a third and fourth pressure sensor is not merely duplicating parts as the Examiner suggests.

The Examiner concludes that it would have been obvious to combine Cowan's pressure sensors into a differential pressure sensor because such a sensor involves combining discrete units into a differential pressure sensor, and it has been held that forming in one piece an article that has formerly been formed in multiple pieces and put together involves only routine skill in the art. Appellant respectfully disagrees. The Examiner's logic makes no sense. The Examiner's logic might make sense if Appellant claimed a pressure sensor that was made of one piece, and the prior art showed a pressure sensor that was made of two pieces. But in Cowan, the two pressure sensors are located a distance apart from one another. One is inside the master control unit housing

and one is outside of the housing. Appellant fails to see how these two spaced apart pressure sensors can be combined into one differential pressure sensor that is located within the housing without the use of hindsight. Such a modification of Cowan's device does not involve just routine skill, and would not have been obvious to one of ordinary skill in the art.

Finally, Appellant also points out that dependent claims 41-46 recite that the first and second pressure sensors are disposed on a common substrate and the CPU is disposed on the common substrate, or that the differential pressure sensor and the CPU are disposed on a common substrate. There is no teaching or suggestion in Cowan of such a structure. For example, as discussed above, Cowan's two pressure sensors are located a distance apart from one another, one inside the master control housing and one outside of the housing. These two sensors clearly are not disposed on a common substrate.

5. Claims 15-17 and 34-36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cowan in view of U.S. Patent No. 6,061,596 to Richmond et al ("Richmond").

The Examiner admits that Cowan fails to teach or suggest a power source comprising RF, acoustics or optics. The Examiner is relying on Richmond for a teaching of an implanted medical stimulator that uses RF, acoustic or optics to power the implanted device and concludes that it would have been obvious to replace Cowan's battery with an alternate energy source to power the implanted device based on Richmond's teachings.

Cowan teaches in column 4, lines 14-23, that "master control unit 24 is powered by a battery 36" such as those widely used in pacemakers, stimulators, defibrillators and the like. Despite the knowledge of those skilled in the art at the time of Cowan's invention regarding externally powering an implanted device, Cowan makes no mention or suggestion that his device can be powered non-invasively.

Richmond is directed to an implanted microstimulator for treating urinary incontinence. This microstimulator thus must use small implantable stimulators that are implanted in or near the pelvic floor muscles to provide "conditioning stimulation on a regular, ongoing schedule." See Richmond column 2, lines 49-54. While understanding

that the term "small" is a relative term, but Richmond discloses in column 3, lines 12-13, that his microstimulator is only "2 mm diameter by 13 mm length." Thus, Richmond's microstimulator is too small to be powered by a battery. In addition, because Richmond's microstimulator must provide regular ongoing stimulation, power must be applied externally because a battery in the implant would drain of sufficient power too soon. Thus, one of ordinary skill in the art would not have found it obvious to turn to Richmond for a reason to substitute Cowan's battery with an external power source because Cowan is not facing the same problems that Richmond is, namely a very small device that must provide stimulation on a regular, ongoing schedule.

Conclusion:

For the reasons discussed above, Appellants maintain that the Examiner's final rejection of claims 1-46 under 35 USC §112, 102(b) and 103(a) should be reversed.

Respectfully submitted,

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CLAIMS APPENDIX

1. (original): An implantable medical device comprising:

a housing;

a valve disposed within said housing;

a first pressure sensor disposed within said housing and upstream of said valve;

a second pressure sensor disposed within said housing and downstream of said valve; and

a CPU disposed within said housing and being operatively connected to said first pressure sensor and said second pressure sensor.

2. (original): The device according to claim 1, wherein the CPU is electrically connected to said first pressure sensor and said second pressure sensor.

3. (amended): The device according to claim 2, wherein the CPU has means for wirelessly communicating within an external device.

4. (amended): The device according to claim 3, wherein the CPU has means for calculating a differential pressure between the first pressure sensor and the second pressure sensor.

5. (amended): The device according to claim 1, wherein the CPU has means for calculating a differential pressure between the first pressure sensor and the second pressure sensor.

6. (original): The device according to claim 1, further comprising a first catheter fluidly connected to said housing, and a third pressure sensor disposed within said first catheter.

7. (original): The device according to claim 6, wherein said third pressure sensor is operatively connected to said CPU.

8. (original): The device according to claim 7, wherein said first catheter is fluidly connected to said housing upstream of said valve.

9. (amended): The device according to claim 8, wherein the CPU has means for wirelessly communicating with an external device.

10. (amended): The device according to claim 9, wherein the CPU has means for calculating a differential pressure between the first pressure sensor and the second pressure sensor, and for calculating a differential pressure between the third pressure sensor and at least one of the first pressure sensor and the second pressure sensor.

11. (original): The device according to claim 10, further comprising a second catheter fluidly connected to said housing, and a fourth pressure sensor disposed within said second catheter.

12. (original): The device according to claim 11, wherein said fourth pressure sensor is electrically connected to said CPU.

13. (original): The device according to claim 12, wherein said second catheter is fluidly connected to said housing downstream of said valve.

14. (amended): The device according to claim 13, wherein the CPU has means for calculating a differential pressure between the first pressure sensor and the second pressure sensor and for calculating a differential pressure between the fourth pressure sensor and at least one of the first pressure sensor, the second pressure sensor and the third pressure sensor.

15. (amended): The device according to claim 1, wherein the CPU has means for being non-invasively powered using RF.

16. (amended): The device according to claim 1, wherein the CPU has means for being non-invasively powered using acoustics.

17. (amended): The device according to claim 1, wherein the CPU has means for being non-invasively powered using optics.

18. (original): An implantable medical device comprising:

a housing;

a valve disposed within said housing;

a first pressure sensor disposed within said housing and upstream of said valve;

a second pressure sensor disposed within said housing and downstream of said valve; and

a CPU being operatively connected to said first pressure sensor and said second pressure sensor.

19. (original): The implantable medical device according to claim 18, wherein said CPU is disposed within said housing.

20. (original): The implantable medical device according to claim 18, wherein said CPU is disposed external to said housing.

21. (original): A method for diagnosing the performance of an implanted medical device, wherein the implanted medical device has:

a housing;

a valve disposed within said housing;

a first pressure sensor disposed within said housing and upstream of said valve;

a second pressure sensor disposed within said housing and downstream of said valve; and

a CPU disposed within said housing and being operatively connected to said first pressure sensor and said second pressure sensor,

the method comprising the steps of:

comparing the pressure measured by the first pressure sensor to the pressure measured by the second pressure sensor; and

wirelessly communicating the compared pressures to an external device.

22. (original): The method according to claim 21, wherein the device further has a first catheter fluidly connected to said housing, and a third pressure sensor disposed within said first catheter, said method further comprising the steps of:

comparing the pressure measured by the third pressure sensor to one of the pressure measured by the first pressure sensor and second pressure sensor.

23. (original): The method according to claim 22, wherein the device further comprising a second catheter fluidly connected to said housing, and fourth pressure sensor disposed within said second catheter, said method further comprising the step of:

comparing the pressure measured by the fourth pressure sensor to one of the pressure measured by the first pressure sensor, the second pressure sensor and third pressure sensor.

24. (original): A method of diagnosing the performance of an implanted medical device wherein the implanted medical device has:

a housing;

a valve disposed within said housing;

a first pressure sensor disposed within said housing and upstream of said valve;

a second pressure sensor disposed within said housing and downstream of said valve; and

a CPU disposed within said housing and being operatively connected to said first pressure sensor and said second pressure sensor,

the method comprising the steps of:

determining by the CPU, the pressure detected by the first pressure sensor;

determining by the CPU, the pressure detected by the second pressure sensor; and

wirelessly communicating the determined pressures to an external device.

25. (original): An implantable medical device comprising:

a housing;

a valve disposed within said housing;

a differential pressure sensor disposed within said housing ; and

a CPU disposed within said housing and being electrically connected to said differential pressure sensor.

26. (amended): The device according to claim 25 wherein the CPU has means for wirelessly communicating within an external device.

27. (original): The device according to claim 25, further comprising a first catheter fluidly connected to said housing, and a second pressure sensor disposed within said first catheter.

28. (original): The device according to claim 27, wherein said second pressure sensor is operatively connected to said CPU.

29. (original): The device according to claim 28, wherein said first catheter is fluidly connected to said housing upstream of said valve.

30. (amended): The device according to claim 29, wherein the CPU has means for wirelessly communicating within an external device.

31. (original): The device according to claim 30, further comprising a second catheter fluidly connected to said housing, and a third pressure sensor disposed within said second catheter.

32. (original): The device according to claim 31, wherein said third pressure sensor is operatively connected to said CPU.

33. (original): The device according to claim 32, wherein said second catheter is fluidly connected to said housing downstream of said valve.

34. (amended): The device according to claim 25, wherein the CPU has means for being non-invasively powered using RF.

35. (amended): The device according to claim 25, wherein the CPU has means for being non-invasively powered using acoustics.

36. (amended): The device according to claim 25, wherein the CPU has means for being non-invasively powered using optics.

37. (original): A method of diagnosing the performance of an implanted medical device wherein the implanted medical device has:

a housing;

a valve disposed within said housing;

a differential pressure sensor disposed within said; and

a CPU disposed within said housing and being electrically connected to said differential pressure sensor,

the method comprising the steps of:

determining by the CPU, the pressure detected by the differential pressure sensor; and

wirelessly communicating the determined pressure to an external device.

38. (original): A method for diagnosing the performance of an implanted medical device, wherein the implanted medical device has:

a housing;

a valve disposed within said housing;

a first pressure sensor disposed within said housing and upstream of said valve; and

a second pressure sensor disposed within said housing and downstream of said valve;

the method comprising the steps of:

wirelessly communicating a signal representative of the pressure detected by the first pressure sensor to an external device;

wirelessly communicating a signal representative of the pressure detected by the second pressure sensor to an external device; and

comparing the pressure detected by the first pressure sensor to the pressure detected by the second pressure sensor with the external device.

39. (original): A method for diagnosing the performance of an implanted medical device, wherein the implanted medical device has:

a housing;

a valve disposed within said housing;

a first pressure sensor disposed within said housing and upstream of said valve; and

a second pressure sensor disposed within said housing and downstream of said valve;

the method comprising the steps of:

generating a signal from the first pressure sensor;

generating a signal from the second pressure sensor;

comparing the signals from the first pressure sensor and the second pressure sensor;

generating a signal representative of the difference in pressure between the pressure measured by the first pressure sensor and the pressure measured by the second pressure sensor;

wirelessly communicating the signal representative of the difference in pressure to an external device.

40. (original): An implantable medical device comprising:

a housing;

a valve disposed within said housing;

a first pressure sensor disposed within said housing and upstream of said valve; and

a second pressure sensor disposed within said housing and downstream of said valve.

41. (new): The device according to claim 1, wherein said first pressure sensor and said second pressure sensor are disposed on a common substrate.

42. (new): The device according to claim 41, wherein said CPU is disposed on said common substrate.

43. (new): The device according to claim 18, wherein said first pressure sensor and said second pressure sensor are disposed on a common substrate.

44. (new): The device according to claim 43, wherein said CPU is disposed on said common substrate.

45. (new): The device according to claim 25, wherein said differential pressure sensor and said CPU are disposed on a common substrate.

46. (new): The device according to claim 40, wherein said first pressure sensor and said second pressure sensor are disposed on a common substrate.

EVIDENCE APPENDIX

No evidence has been submitted by Appellant pursuant to 37 C.F.R. §§ **1.130**, **1.131**, or **1.132** during the prosecution of this application. Nor has any other evidence been entered by the Examiner and relied upon by Appellant in the appeal.

RELATED PROCEEDINGS APPENDIX

Pursuant to 37 C.F.R. 41.37(c)(1)(ii), Appellant, the Appellant's legal representative, or the Assignee is not aware of any decisions that have been rendered by a court or the Board in any proceeding that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.